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| 10/517,903 | 12/10/2004 | Michael G Willits | 70058USPCT | 4683 |

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| EXAMINER |
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ROBINSON, KEITH O NEAL

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| ART UNIT | PAPER NUMBER |
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1638

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07/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,903

Applicant(s)

WILLITS ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 11-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/13/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-10) in the reply filed on May 2, 2007 is acknowledged. The requirement is made FINAL.
2. Claims 11-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 2, 2007.
3. Claims 1-10 are under examination.

Claim Objections

4. Claims 8-10 are objected to because of the following informalities: Claims 8 and 9 should begin with the word "A" and claim 10, line 1 should read - - or a part thereof, - - because only a single invention can be claimed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The claims read on any non-transgenic domesticated *L. esculentum* plant having flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

See MPEP 2163(I) where it states "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116".

Based on the evidence disclosed in the specification, it appears that Applicant is not in possession of any non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt. The specification states that "*L. pennellii v. puberulum* (LA1926) shows strong expression of all investigated flavonol biosynthetic genes in both the fruit peel and flesh...[and thus,]... *L. pennellii v. puberulum* (LA1926) was chosen as a crossing partner to introgress flavonol production into *L. esculentum*" (see page 10, lines 22-25); however, the specification does not show that Applicant was in possession of a *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

Also see MPEP 2163.02 where it states, "[a]n objective standard for determining compliance with the written description requirement is, "does the description clearly

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allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989”).

In the instant invention, one of ordinary skill in the art would only recognize that Applicant has invented any non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

MPEP 2163.02 further states, “[u]nder *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed”.

In the instant case, Applicant has not conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of any non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

The only non-transgenic *Lycopersicon* lines that showed flavonol content in the flesh of the fruit were LA1963, LA2884 and LA1926; however, none of these lines were *L. esculentum* plants. In addition, Applicant shows a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid that possesses flavonol content in the flesh of the fruit, but it does not appear to be a non-transgenic domesticated *L. esculentum* plant (see page 14, Table 3), but Willits et al (J Agric Food Chem 53: 1231-1236, 2005) teach, “[i]t turned out to be difficult to produce tomatoes from these crosses, and the fruit was invariably seedless...it was not possible to further analyze progeny from the F1 hybrid...a

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breeding program to remove interspecific breeding barriers between *L. pennellii* and *L. esculentum* is required in order to obtain fertile hybrids for subsequent analysis of the high flavonoid trait in the next generation" (see page 1235, 1st column, 1st full paragraph).

Therefore, it is unclear how Applicant was in possession of a non-transgenic domesticated *L. esculentum* plant having flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt when the prior art teaches that it was not possible to further analyze progeny from the F1 hybrid because of interspecific breeding barriers between *L. pennellii* and *L. esculentum*.

Thus, based on the disclosure of the specification, Applicant has not shown possession any non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Goffreda et al (Theor Appl Genet 78: 210-216, 1989). The claims read on any non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

The specification states, "the introduction of the genetic factors from *L. pennellii* into the hybrid plant results in the expression of the flavonol biosynthetic genes and subsequent production of flavonols and flavonol glucosides in the peel and also in the flesh" (see page 14, lines 11-14). Thus, the claims are interpreted as any tomato plant having genes introgressed from *L. pennellii*.

Goffreda et al disclose a *L. esculentum* plant having genes introgressed from *L. pennellii* (see page 212, Tables 1-3) and thus, would inherently possess a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt based on the disclosure of the specification as stated above.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

9. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al (J Agric Food Chem 48: 2663-2669, 2000). The claims read on any non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

Stewart et al disclose non-transgenic domesticated *L. esculentum* plants having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt (see page 2667, Table 2).

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is (571) 272-2918. The examiner can normally be reached Monday - Friday 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

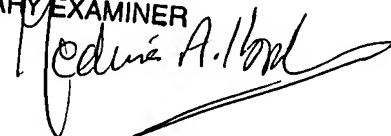
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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.

July 5, 2007

MEDINA A. IBRAHIM
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Medina A. Ibrahim", written over the printed name and title.